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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,039	09/22/2003	Laurier Falldien	DWE/MAGIC DRAGON/FALLDIEN	6572
32834	7590	01/03/2005		EXAMINER
D.W. EGGINIS 18 DOWNSVIEW DRIVE BARRIE, ON L4M 4P8 CANADA			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,039	FALLDIEN, LAURIER	
	Examiner	Art Unit	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 October 2004 and 22 September 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 12-14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 5-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed October 5, 2004, has been received and entered. The declaration of Laurier Falldien and arguments submitted September 22, 2004 have been received and considered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-14 are pending.
3. In the reply filed on June 3, 2004, applicant elected Group II, claims 5-11 without traverse.
4. Claims 1-4 and 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 3, 2004.
5. Claims 5-11 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of periodontal infection, aphous ulcers, herpes simplex, and gingivitis, does not reasonably provide enablement for oral bone regeneration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are directed towards a composition used to regenerate oral bones. Applicant's specification does not provide any evidence or data that supports this intended use of the composition. In addition, the related art teaches that bone grafts and tissue stimulating proteins are needed to actually achieve oral bone regeneration (see www.dentistry.com/perio003.asp and www.perio.org/consumer/regeneration.htm). The related art does not acknowledge using oral rinses such as those claimed will cause bone to regrow. Thus, since applicant has not shown that the inventive composition functions to regenerate bone and because the related art teaches using completely different methods than claimed, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if the claimed composition functions as claimed.

7. Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is indefinite because the claim states that the composition is "for use as a prophylaxis application in the treatment...". The term "prophylaxis" implies that the patient has not yet acquired the condition; however, the term "treatment" implies that the patient already has acquired the condition. This conflict is confusing. In addition, the statement "for use as a

prophylaxis application in the treatment for...oral bone regeneration" is unclear. This combination or prophylaxis and/or treatment with "oral bone regeneration" is confusing because "oral bone regeneration" is not something that would be beneficial to prevent or treat. Oral bone regeneration is beneficial and would be stimulated not prevented or treated.

Claim Rejections - 35 USC § 103

8. Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,472,684 in view of US Pat. No. 6,290,417 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the prior art does not teach the claimed invention because the prior art does not teach treatment for periodontal infection, oral bone regeneration, aphous ulcers, herpes simplex, and gingivitis. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For the reasons discussed in the previous Office action, the prior art is considered to teach a composition that is the same as applicant's claimed composition. Since the prior art teaches a composition that is the same, any properties in the

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claimed composition would be found in the composition taught by the combination of the prior art.

Applicant also argues that the use of the containers is important because the claimed containers protect the composition from photo-induced changes. However, applicant is claiming a composition, not a method of storing a composition. Placing a composition in packaging does not effect the basic properties of the composition. The composition is the same no matter if it is placed in a bottle or a bag or a box. Thus, the references are considered to teach the claims even though they do not specifically teach the claimed containers.

Applicant also argues that the declaration submitted on September 22, 2004 shows that the composition has beneficial and unexpected results in regards to the ability of the composition to treat conditions such as periodontal infection. However, applicant's declaration only shows that the invention functions in these manners. No comparison is done with prior art compositions to show that the results truly are unexpected. In addition, US '684 teaches that compositions that contain comprises glycerin, tea tree oil, peppermint oil, and water have antiplaque, antigingivitis, and antibacterial properties. Thus, it is not unexpected that the composition exhibits these effects. Furthermore, since the prior art teaches combining the claimed ingredients together, any effects on oral diseases would be found in the composition taught by the prior art.

Applicant also argues that there is no motivation in the art to combine the ingredients together. However, as discussed in the previous Office action, the prior art is considered to provide appropriate motivation for combination of the claimed ingredients. US '684 teaches a composition for oral cleansing that comprises glycerin, tea tree oil, peppermint oil, and water

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(see Tables 12 and 16). However, the reference does not specifically teach adding sea salt to the composition. US ‘417 teaches that sea salt is used in oral cleansing (see column 4, line 15). As discussed in MPEP section 2144.06, “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” Thus, it would be obvious for a person of ordinary skill in the art to combine sea salt with glycerin, tea tree oil, peppermint oil, and water.

9. Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. Pub. No. 2003/0031730 in view of European Pat. Appl. No. 1108422 A2 for the reasons set forth in the previous Office action.

All of applicant’s arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant has combined the traversal of this rejection with the traversal of the rejection based on US ‘684 and US ‘417. Thus, a response to these arguments can be found above. In addition, in regards to the motivation to combine US ‘730 with EP ‘422, as discussed in the previous Office action, US ‘730 teaches a nasal passage cleansing composition that comprises water, tea tree oil, peppermint oil, glycerin, and sodium chloride (see Table 1). While the reference does teach using salt it does not specifically teach using sea salt. EP ‘422 teaches that sea salt can be used interchangeably with sodium chloride in a nasal cleansing composition (see English abstract). Thus, based on this disclosure of the interchangeable nature of sea salt and sodium chloride, a person of ordinary skill in the art would reasonably expect that sea salt would function equivalently to the sodium chloride in the

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composition of US '730. Based on this equivalence, a person of ordinary skill in the art would be motivated to substitute sea salt for sodium chloride in US '730.

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe
12-29-04

Susan D. Coe
Primary Examiner
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